ARNAUD GUILLET, BIOCORP

Arnaud Guillet is Business Development Associate at Biocorp, in charge of finding partnerships and license opportunities for Biocorp's range of connected devices. Previously, Guillet worked for a healthcare consulting firm with a strong focus on connected health strategies for pharma and insurance companies and has additional past experience in the pharmaceutical industry (with Sanofi) and the insurance industry (with AXA). He graduated from HEC Paris, a major European business school.

In this interview, Mr Guillet discusses Biocorp's existing connected device offering, how it delivers value for the company's pharmaceutical partners, the development of the accompanying software and data architecture, and how Biocorp has very significant opportunities to leverage its triple expertise in medical devices, electronics and software further.

Q Starting with some background on Biocorp's business, please could you broadly describe Biocorp's connectivity offering specifically in the context of Biocorp's overall business model and commercial strategy?

A Biocorp offers two types of connected solutions, integrated solutions and what we call add-ons.

Integrated solutions are actual drug delivery devices natively connected, developed from scratch, and their form, shape and process are like regular products on the market, but they incorporate electronics and can communicate treatment information in real time to a mobile app or data platform.

Add-ons are smart sensors that can be attached to regular devices on the market, turning them into connected products. Typically these require no modification to the existing devices and have no impact on the regulatory and industrial processes.

On the device side, our strategy is to develop mature technical products and then we customise these products based on our partners' needs and the specific requirements of each pathology. We handle the full development of the device from conception to final validation, and we manufacture and assemble the products in our facilities.

For the software side, we are highly flexible. Depending on the requirements of our partners, we can either undertake the development of the software ourselves, using our own architecture. Or we can connect our devices to existing data platforms or apps. In both cases, Biocorp's software teams are highly involved of course to ensure that, for example, data transfer, storage and access are secure, continuous and accurate.

> "You can boost usage further by working on interoperability with other successful digital platforms, which automatically maximises the benefits of connectivity."

We already have several development programs in motion using our proprietary technologies with major pharma and biotech companies.

Q Biocorp is developing connectivity technology across both the parenteral and respiratory areas. Please could you tell us about what you are doing in each of these two areas, what technologies are you developing?

A In the parenteral area we have two main products. The first is the Datapen® (Figure 1), a re-usable electromechanical pen that uses standard cartridges. In terms of usage, it's like a regular pen although we offer additional functionalities to guide the patient. All treatment information is recorded and automatically transmitted to a mobile app via Bluetooth. This brings additional benefits beyond connectivity. For instance, electromechanical injection allows highly accurate dose delivery and additional comfort and stability for the patient. Thanks to the screen, we can provide visual information to guide the patient and indicate the process step by step.

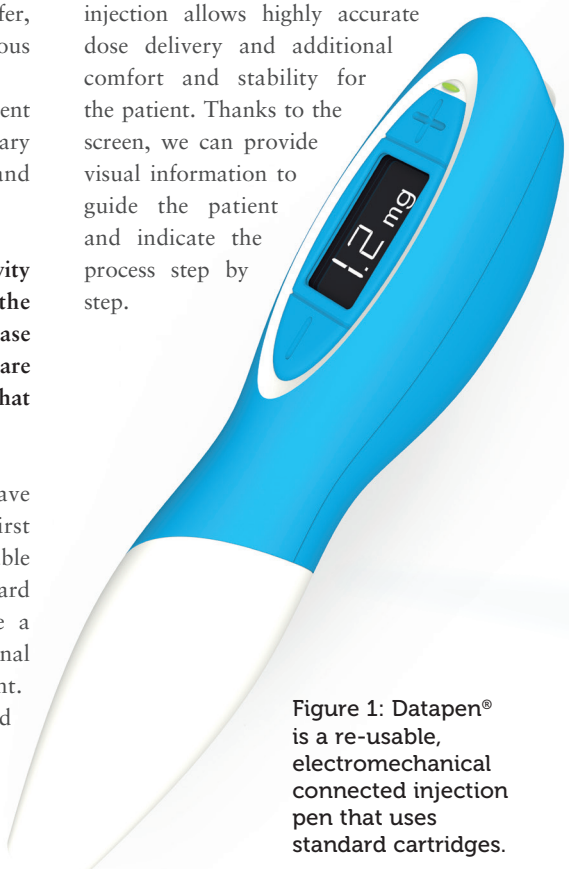

Figure 1: Datapen® is a re-usable, electromechanical connected injection pen that uses standard cartridges.

Our second parenteral product is the Easylog® (Figure 2). This is an add-on solution that quickly brings connectivity to regular pen injectors. It can be adapted to any pen injector on the market, whether disposable or re-usable. The patient attaches Easylog® to the pen and it automatically records each injection – the dose, time and date – and transfers that information in real time to the mobile app. It's really about automatic transferability, with very high accuracy levels. It's seamless and effortless for the patient, who can keep their existing device yet benefit instantly from connectivity features. It's also very easy to implement for pharma companies because it does not impact on existing devices and does not require any significant change for the regulatory and industrial process.

Easylog®, which can be customised to fit requirements, is already at an advanced stage of development thanks to several partnerships in different therapeutic areas.

On the inhalation side, we recently launched Inspair® (Figure 3) which is a smart sensor for inhalers that not only records each delivery of the dose, but also monitors hand-breath co-ordination for proper inhalation technique, and it also provides feedback to patients about their technique. Therefore it's designed not just as a treatment monitoring solution but as an education tool to highlight the importance of inhalation technique, which is a key factor when it comes to inhalers. Each inhalation curve and application of pressure on the canister (to actuate the dose) is recorded and displayed on a dedicated mobile app so the patient can check if their co-ordination was optimal.

Figure 2: Easylog® is an add-on solution that quickly brings connectivity to any regular pen injector, whether disposable or re-usable.

"Another very important point, sometimes forgotten, is about supporting adoption of digital tech by pharma, especially the with regard to the data. This is not their environment, they are not digital data companies. All of this real life data can be extremely valuable for pharma."

Figure 3: Inspair® is a smart sensor for inhalers that records each dose delivery, monitors hand-breath co-ordination and provides feedback to patients on technique.

Q **In the past, the drug delivery business had a tendency to become segmented into different classes of delivery system or different technologies that address specific routes of delivery, often with little interaction between the different sub-disciplines. Connectivity cuts across these divisions, with Biocorp – working in both parenterals and inhalables – representing a prime example. I wondered if you could talk a little about the similarities, and the differences, when it comes to connectivity technology for the parenteral and respiratory sectors?**

A Of course all connected devices are facing some very similar challenges. We're talking about improving treatment adherence and patient experience. This can only be achieved by designing solutions that easily integrate, facilitate treatment monitoring and help patients to use their device properly. This is why at Biocorp we have always developed our devices with this type of benefit in mind – accurate and automatic tracking solutions plus the guarantee of proper use of the device.

For all therapeutic areas you need to record every dose delivery together with the time and date. You need to set up reminders to avoid missing doses, and provide guidance to ensure full patient engagement. I think this is a key part of any connected offering, across all therapeutic areas.

But of course you also need to consider the different requirements from one pathology to another. This is why typically we have a platform and know-how about gathering information from existing devices and we are leveraging this platform for bioscience applications.

Parenteral and inhaled products have different requirements and so for each pathology we prioritise the functionalities that matter to patients and healthcare practitioners (HCPs). For example, in the injection field, accuracy of delivery and precision of information recorded is a key topic. This is why we designed the Easylog to record the exact dose delivered automatically. On the other hand, for inhalable drugs, rather than very precise

recording of the amount of drug delivered, the key challenge is more about inhalation technique and proper use of the device. So this is why Inspair™ records pressure on the canister, and the inhalation curve, to support patients in their use of their inhalers.

When it comes to connected solutions, you don't want the patient to be overwhelmed with information. You start from a common basis and then put in only the key functionalities that bring true value to the patient.

Q I have heard it said several times by people working in the industry that adding the communication tech itself to drug delivery devices is the "easy" part of creating a connectivity offering. To what extent do you agree with this? What do you think are the most challenging aspects, and how does Biocorp differentiate itself from others in the space as it meets those challenges?

A It's an interesting remark and I would say that I only partially agree, because of course there are many challenges beyond the communication tech itself, for instance software development, data and apps, patient adoption, pharma adoption as well. However, the communication tech itself can be challenging because it implies changing the initial device somehow, a device with which the patient is already familiar, which regulatory approval has been obtained, and for which an industrialisation process has been built.

It's quite challenging to add this communication tech with minimal impact on the patient (same user process, same number of steps etc). And you must not impact the regulatory pathway, nor the industrial process. So if we're talking about a connectivity integrated device, for example a re-usable pen injectors, you need to make this compatible with standard cartridges. It also needs to be as close as possible to the shape and process of existing devices. Similarly for add-ons, these must not affect the device usage and must not come into contact with the drug, and they must guarantee discreet and elegant integration. Once they are on the device, there must not be any additional use steps.

All of this has to be kept in mind when integrating the communication tech, and this is why Biocorp can leverage its 20 years of experience in the development and manufacture of medical devices. We're familiar with all these requirements. We are also pioneers in electronic and connected solutions and we know all of the criteria we need to meet to integrate the tech with the medical device.

Once you have successfully integrated the tech, then you have to take care of the software. There are essentially two aspects of the software, the data and the app. For the data you must guarantee 100% data security – this is crucial for patients, HCPs and regulators. Once the data leaves the device it must be encrypted and transferred to the data platform located in a certified data hosting server. No data should be stored on the smartphone and patients must be authenticated before accessing their information through the app. If pharma wants to access their patients' data, they must be anonymised and delivered in a statistical format.

For the app, you have to design an easy-to-use, highly visual and intuitive app with only the most valuable functionality for the patients. The design is really crucial for us, and we ultimately guarantee sustainable usage over time.

When these first two steps have been completed successfully – seamless communication tech integration with the delivery device, and the software and app with relevant content – you can foresee good patient adoption. Then you can boost usage further by working on interoperability with other successful digital platforms, which automatically maximises the benefits of connectivity.

Another very important point, sometimes forgotten, is about supporting adoption of digital tech by pharma, especially the with regard to the data. This is not their environment; they are not digital data companies. All of this real life data can be extremely valuable for pharma, but there are two challenges that you need to have in mind: access to data and capacity to exploit data. Pharma are not allowed to access personal data. Therefore, Biocorp has developed a data processing system to anonymise and deliver data to pharma companies in a statistical format, which is exploitable by pharma. We then work with

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Q Whilst connectivity is certainly emerging rapidly and very strongly in the drug delivery business (and elsewhere), careful attention needs to be paid to the value proposition. "Connectivity for connectivity's sake" is not enough. What is Biocorp's value proposition to the industry?

A We're working, together with our pharma partners, to develop the best solutions tailored for specific business cases. Improving clinical outcome is the final objective but different ways are open to reach that goal and different steps to climb. First, have the patients equipped with the system, then be sure they will use the device in the long-run by working on the user experience and the benefits the user can gather from using the technology. Then ensure that the pharma company can achieve a return on investment in the technology. This could be from improved clinical outcomes and/or better adherence, better quality of life.

Q Finally, I wondered if you could tell us what lies ahead for Biocorp in the short, medium and longer term? What are the general trends and drivers impacting on the business, any short-term upcoming milestones, and any longer-term business objectives and strategy goals?

A In the short-term we already have exciting ongoing partnerships with pharma companies for our current line of products in various therapeutic areas including diabetes, growth hormones, Parkinson's disease, rare diseases, asthma and COPD, so we would like to keep expanding into the many additional therapeutic areas where our products are applicable, and keep increasing their potential through various partnerships in terms of functionality, desirability, and design etc.

Beyond our current line of products, we want to use our triple expertise – in medical devices, electronics and software – to support our customers in their future projects. Whatever the product, the packaging, or the delivery system, we can design and build a connected solution. We are reviewing the potential of many different types of drug delivery system, beyond inhalation and injection, there are a lot of companies coming to us with projects involving different delivery systems and this is really exciting for us and somewhere we can identify many new opportunities. We already answer specific needs and we have some specific *ad hoc* projects in the pipeline, and we would like to continue doing this.

In the long-term, Biocorp's DNA is obviously innovation so we invest significantly in R&D to anticipate future needs and develop solutions to meet these needs in various therapeutic areas.

In parallel to all of these efforts we're building a network to guarantee sustainable use of the connectivity features we develop. We're continually working on our compatibility and our interoperability with existing and emerging digital platforms to make sure patients using our devices can maximise the connectivity benefits. One of the possibilities is to cross over information, for example. So we ensure that our apps and platforms will not be isolated from the digital healthcare ecosystem but, on the contrary, highly integrated with it, which can guarantee usage and success over time.

I believe we are right at the beginning of the wave of connectivity in this area and maybe, in ten years' time, every type of delivery system will somehow be connected.

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ABOUT THE COMPANY

For 20 years, Biocorp has been designing, developing and manufacturing medical devices for the pharmaceutical industry, enhancing drug reconstitution, safety, packaging and delivery. Today, Biocorp continues to innovate in medical plastics, bringing new solutions to the market such as the Newguard™, an integrated passive safety system for PFS compatible with nest, and the Biopass, a reconstitution system with an integrated needle ready to inject.

Recognised for its expertise in device R&D, Biocorp has incorporated software development capacities to develop connected drug delivery systems, including the DataPen®, a reusable smart pen injector that automatically transmits data to a treatment mobile app, helping patients to manage their treatment, and a range of add-ons, smart sensors for existing drug delivery devices (pen injectors, MDIs).

In addition to its R&D activities, Biocorp also provides manufacturing services for plastic injection, process assembly and blister packaging.

BIOCORP

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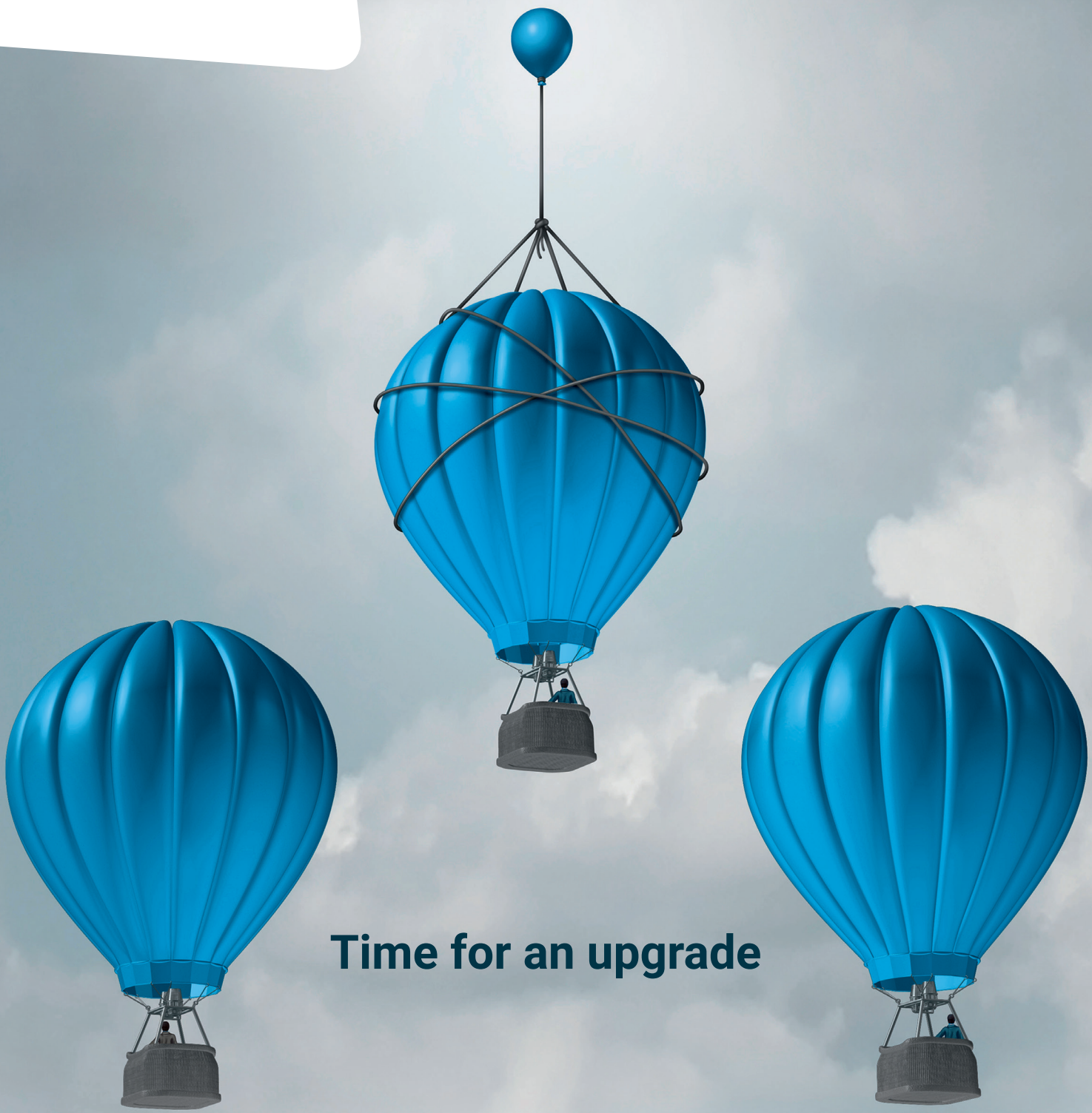
BIOCORP

Design • Develop • Manufacture Medical Devices



Time for an upgrade

Give your existing device the benefit of connectivity.

With over 20 years of designing and manufacturing medical devices for the pharmaceutical industry, Biocorp knows precisely how connectivity gives you better data, leading to better treatment and better patient outcomes.

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